



25-12-04

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By: Barbara Bryant Date: May 11, 2004
Barbara Bryant

PATENT
Attorney Docket No. P-025-US4
Customer Number 27038

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | |
|---------------------------------|---|----------------------------------|
| In re Patent Application of |) | |
| |) | |
| Edmund J. MORAN |) | Group Art Unit: Not yet assigned |
| |) | |
| Application No.: 10/769,219 |) | Examiner: Not yet assigned |
| |) | |
| Filed: January 30, 2004 |) | |
| |) | |
| For: BETA 2-ADRENERGIC RECEPTOR |) | |
| AGONISTS |) | |
| |) | |

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure as set forth in 37 CFR §1.56, Applicants hereby submit the following information in conformance with CFR §§1.97 and 1.98.

Enclosed herewith is a form PTO/SB/08a which lists documents for consideration by the Examiner. Copies of the cited documents are also enclosed herewith.

The filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made (37 C.F.R. §1.97(g)), or as an admission that the information cited is, or is considered to be, material to patentability (37 C.F.R. §1.97(h)).

Consideration of the listed documents is respectfully requested. Additionally, the Examiner is respectfully requested to return an initialed copy of the enclosed form PTO/SB/08a to Applicant with the next communication in this application.

Pursuant to 37 C.F.R. §1.98(a)(3)(i), a concise explanation of the relevance of the following non-English language documents are provided:

- (1) CH 550 768 (in German) is believed to disclose bis[(4-hydroxy-3-hydroxymethylphenyl)ethanol diamine derivatives. An English-language abstract is also enclosed for this document.
- (2) DE 1158 082 (in German) is believed to disclose N,N'-diphenylethylethylene diamine and N,N'-diphenylethyltetramethylene diamine. An English-language abstract is also enclosed for this document.
- (3) DE 1215729 (in German) is believed to disclose bis-phenylalkylamines. An English-language abstract is also enclosed for this document.
- (4) JP 10152460 (in Japanese) is believed to disclose 2-amino-1-(4-hydroxy-2-methylphenyl)propanol derivatives. An English-language abstract is also enclosed for this document.
- (5) Auterhoff et al., (in German) is believed to disclose pharmaceutical compounds used in treatment of conditions caused by the β_2 adrenergic receptor, including salbutamol, and hexoprenalin.
- (6) Stormann et al., (in German) is believed to disclose the stimulating effects of hexoprenaline on various sympathetic β -receptors. An English-language abstract is also enclosed for this document.

Copies of the U.S. patents and patent application publications cited on the accompanying PTO Form 1449 have been omitted in accordance with the notice published August 5, 2003 in the Official Gazette 55, stating that the requirement under 37 CFR 1.98 (a)(2) for submitting such copies has been waived for U.S. national patent applications filed after June 30, 2003.

This Information Disclosure Statement is being filed before the mailing date of a first official action on the merits for this application and therefore, no fee or certification is required under 37 CFR §1.97(b). In the event that an Office Action is mailed prior to receipt

of this paper, the Commissioner is hereby authorized to charge the requisite fees under 37 CFR §1.97(c) for submission of this paper to Deposit Account No. 50-0344.

Should there be any questions concerning the cited document, the Examiner is encouraged to telephone the undersigned agent for Applicants at (650) 808-6144.

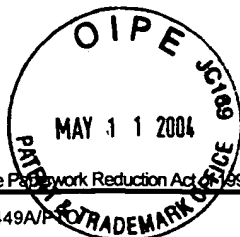
Respectfully submitted,

THERAVANCE, INC.

Date: May 11, 2004

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PTO/SB/08a (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

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Substitute for form 1449A/P

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known

| | |
|------------------------|------------------|
| Application Number | 10/769,219 |
| Filing Date | January 30, 2004 |
| First Named Inventor | Edmund J. Moran |
| Art Unit | Not yet assigned |
| Examiner Name | Not yet assigned |
| Attorney Docket Number | P-025-US4 |

U.S. PATENT DOCUMENTS

| Examiner Initials * | Cite No. ¹ | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|------------------------|--------------------------|--|--------------------------------|--|---|
| | | Number - Kind Code ² (if known) | | | |
| | A1 | US- 3,211,792 | 10-12-1965 | Osbond et al. | |
| | A2 | US- 3,875,233 | 04-01-1975 | Bastian et al. | |
| | A3 | US- 4,021,485 | 05-03-1977 | Schromm et al. | |
| | A4 | US- 4,304,721 | 12-08-1981 | Fahrenholtz et al. | |
| | A5 | US- 6,362,371 B1 | 03-26-2002 | Moran et al. | |
| | A6 | US- 6,541,669 B1 | 04-01-2003 | Moran et al. | |
| | A7 | US- 6,593,497 | 07-15-2003 | Choi et al. | |

FOREIGN PATENT DOCUMENTS

| Examiner Initials * | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
|------------------------|--------------------------|--|--------------------------------|---|--|----------------|
| | | Country Code ³ - Number ⁴ - Kind Code ⁵ (if known) | | | | |
| | B1 | WO 99/64035 A1 | 12-16-1999 | Advanced Medicine, Inc. | | |
| | B2 | EP 0 233 686 A2 | 08-26-1987 | Beecham Group PLC | | |
| | B3 | CH 550 768 (in German with English abstract) | 06-28-1974 | Sandoz AG | | |
| | B4 | DE 1158 082 (in German with English abstract) | 11-28-1963 | Chemie Grünenthal G.m.b.H. | | |
| | B5 | DE 1215729 (in German with English abstract) | 05-05-1966 | Lentia G.m.b.H. | | |
| | B6 | GB 1,040,724 | 09-01-1966 | Roessler et al. | | |
| | B7 | JP 10152460 (in Japanese with English abstract) | 06-09-1998 | Kissei Pharm Co Ltd. | | |

NON PATENT LITERATURE DOCUMENTS

| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|------------------------|--------------------------|---|----------------|
| | C1 | Alvarez et al., "Structure-Activity Relationships among Di- and Tetramine Disulfides Related to Benextramine", J. Med. Chem., Vol. 30, No. 7, pp 1186-1193 (1987) | |
| | C2 | Auterhoff et al., "Lehrbuch der Pharmazeutischen Chemie", 12th Edition. Stuttgart: Wiss. Verl.-Ges., pp 646-648 (1991) - in German | |
| | C3 | Bastian et al., "Carbocyclic compounds", (5128p), Chemical Abstracts, Vol. 79, pp 433-434 (1973) | |
| | C4 | Bastian, "Carbocyclic compounds", (104935f), Chemical Abstracts, Vol. 79, pp 400 (1973) | |
| | C5 | Colella et al., "N,N'-Bis[2-(4-hydroxyphenyl)ethyl]polymethylene-diamines" (126069d), Chemical Abstracts, Vol. 79, pp 371-372 (1973) | |

Examiner
Signature

Date
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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| | | | |
|---|------------------------|--------------------------|------------------|
| Substitute for form 1449B/PTO | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | Application Number | 10/769,219 |
| | | Filing Date | January 30, 2004 |
| | | First Named Inventor | Edmund J. Moran |
| | | Art Unit | Not yet assigned |
| | | Examiner Name | Not yet assigned |
| Sheet 2 of 2 | Attorney Docket Number | P-025-US4 | |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|-----------------------|---|----------------|
| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| | C6 | Machin et al., "β ₁ -Selective Adrenoceptor Antagonists. 2. 4-Ether-Linked Phenoxypropanolamines", J. Med. Chem., Vol 26, pp 1570-1576 (1983) | |
| | C7 | Pinder et al., "Hexoprenaline: A Review of its Pharmacological Properties and Therapeutic Efficacy with Particular Reference to Asthma", Drugs 14: 1-28 (1977), | |
| | C8 | Schmid et al., "Bis(alkanolamine) derivatives", Chemical Abstracts, Vol. 63 (1965) | |
| | C9 | Schromm et al., "Polymethylenediamines", Chemical Abstracts (57999x), Vol. 78, p 485 (1973) | |
| | C10 | Storrmann et al., "Die Stimulierende Wirksamkeit von Hexoprenalin auf verschiedene sympathische β-Rezeptoren", Arzneimittel-Forschung, 23(1), pp 30-38 (in German with English abstract) (1973) | |
| | C11 | Wismayr et al., "N,N'-Bis[2-3,4-dihydroxyphenyl]-2-hydroxyethyl]-hexamethylenediamine, its optically active form and its salts", Chemical Abstracts (42149p), Vol. 74, pp 333 (1971) | |
| | C12 | Wismayr et al., "N,N'-Bis[2-3,4-dihydroxyphenyl]-2-hydroxyethyl]-hexamethylenediamine and its salts", Chemical Abstracts (35405m), Vol. 75, pp 457-458 (1971) | |
| | C13 | Wismayr et al., "N,N'-bis[2,3,4'-Dihydroxyphenyl]-2-hydroxyethyl]-hexamethylenediamine", Chemical Abstracts (14096s), Vol. 76, pp 347 (1972) | |
| | C14 | Zoelss et al., "Broncholytic N,N'-bis[2-(3,4-dihydroxyphenyl)-2-hydroxyethyl]diaminoalkanes", Chemical Abstracts (87613b), Vol. 74, pp 406 (1971) | |

| | | | |
|--------------------|--|-----------------|--|
| Examiner Signature | | Date Considered | |
|--------------------|--|-----------------|--|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.